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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------|---------------------|------------------|
| 10/797,374 | 03/10/2004 | Jeffrey O. Phillips | 04242350 | 4467 |
| 26565 | 7590 | 09/13/2006 | | |
| MAYER, BROWN, ROWE & MAW LLP | | | EXAMINER | |
| P.O. BOX 2828 | | | CHANG, CELIA C | |
| CHICAGO, IL 60690-2828 | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------|----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/797,374 | PHILLIPS, JEFFREY O. | |
| | Examiner Celia Chang | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 July 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 151-236 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 151-236 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. This application is a continuation of SN 10/722,184. A preliminary amendment was filed on July 21, 2005. Claims 1-150 have been canceled. Claims 151-236 are pending. A restriction was made in the parent prosecution and hereby made again.

2. ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 160, 175-176, 192, 194, 196-197, 219, 221, 229-229 , drawn to composition containing omeprazole, classified in class 514, subclass 339. If this group is elected, a further election of a single species of composition with every ingredient named is also required. Generic/linking claims 151-159, 163-174, 177-191, 193, 195, 198-218, 220, 222-227, 230-236 can be prosecuted together with the elected claims to the extend of omeprazole
- II. Claim 161 drawn to composition containing lansoprazole, classified in class 514, subclass 340. If this group is elected, a further election of a single species of composition with every ingredient named is also required. Generic/linking claims 151-159, 163-174, 177-191, 193, 195, 198-218, 220, 222-227, 230-236 can be prosecuted together with the elected claims to the extend of lansoprazole.
- III. Claim 162, drawn to composition containing lesomeprazole, classified in class 514, subclass 339. If this group is elected, a further election of a single species of composition with every ingredient named is also required. Generic claims 151-159, 163-174, 177-191, 193, 195, 198-218, 220, 222-227, 230-236 can be prosecuted together with the elected claims to the extend of lesomeprazole.
- IV. Claim 155, drawn to composition containing reabeprazole, pantoprazole, pariprazole or leminoprzole, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of these active ingredients and a further election of a single species of composition with every ingredient named is also required. After further election of a single disclosed species, generic/linking claims 151-159, 163-174, 177-191,

193, 195, 198-218, 220, 222-227, 230-236 can be prosecuted together with the elected claims to the extend of the elected species.

- V. Claims 151-159, 163-174, 177-191, 193, 195, 198-218, 220, 222-227, 230-236, drawn to composition of the remaining subject matter, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of composition with the proton pump inhibitor and buffering agent explicitly named is also required.
- VI. Claim 200, drawn to multiple active ingredient compositions, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of composition with the proton pump inhibitor, buffering agent and the further active ingredient i.e. antibacterial agent, etc. explicitly named is also required.

Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions **shall** be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicants are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Each group of invention contain patentably independent and distinct material including proton pump inhibitor, buffering agent and other active ingredient. Unpatentability of any one group of invention does not necessarily mean unpatentability of the other groups of invention. A

search for each group for its specific elements of the composition would not be required for another group which does not have the identical elements of the composition, thus, is not coextensive. The merit of each invention depends on the specific element, carrier and dosage of each composition, thus, must be searched, and examined independently.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Should applicant traverse on the ground that the groups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. In the instant case, then there could have been no patentability of all the claims over US 5,447,918, see col. 14, lines 55-68 example 7 containing omeprazole and calcium carbonate which anticipated group I invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Sept. 7, 2006



Celia Chang
Primary Examiner
Art Unit 1625